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09/864,510	05/24/2001	Gregory Murphy	28122.89	2445

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EXAMINER	
LEWIS, RALPH A	

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3732	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,510	MURPHY ET AL	
	Examiner	Art Unit	
	Ralph A. Lewis	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,29-70,74-95,99-140,146-165 and 168-245* is/are pending in the application.

4a) Of the above claim(s) *155 and 156* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *37-44, 139, 140, 170-176, 179-185, 188-194, 231, 232, 234, 236-238, 240-242* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 1-12, 29-36, 45-70, 74-95, 99138, 146-154, 157-165, 168, 169, 177, 178, 186, 187, 195-230, 233, 235, 239, 243-245.

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 8-12, 29-35, 45-47, 49, 50, 54-70, 74, 75, 79-95, 104-116, 119-138, 146-154, 157-165, 168, 169, 186, 187, 195-216, 218, 220-230, 233 and 235 are rejected under 35 U.S.C. 102(b) as being anticipated by Deslauriers et al (5,255,678).

Deslauriers et al disclose in Figure 2 a balloon device 20 that is shaped and sized to fit within and occupy a patient's left ventricle 40 when inflated. The device further includes a tube 23 in fluid communication with the balloon 20, a valve 24, pressure gauge (column 8, line 65) and syringe 26. The purpose for which applicant intends the balloon device to be used (i.e. a "shaper") fails to impose any objectively ascertainable structural distinctions from the device disclosed by Deslauriers et al. In regard to claim 3, note (column 18, lines 15-18). In regard to claims 29-35 note the different shapes in Figures 9 and 10. In

regard to claim 31, the proportions of Figure 9 meet the "about" limitation. In regard to claims 53 and 78, wall thickness of a balloon member inherently varies as the balloon is expanded. In regard to claims 57, 58, 82, 83, 108, 109, 131, and 132, the Deslauriers et al balloon is capable of being inflated with different types of fluid[1]. In regard to claims 104-116, and 119-123 the knitting of Deslauriers et al meets the claimed shaper limitations and the elastic balloon portion meets the claimed expander limitations. Additionally, in regard to claim 114, Deslauriers et al discloses a fluid (column 12, line 9) capable of being positioned between the knitting and the elastic member. In regard to claims 124-137, the elastic member of Deslauriers et al meets the shaper limitations and the knitting/electrodes of Deslauriers et al meet the "spacer" limitations. In regard to claim 138, note the bumpy portions 12 on the Deslauriers et al expandable balloon that have a thickness greater than the surrounding portions of the balloon. In regard to claims 168 and 169, note column 13, lines 25-28, where the left ventricle is reshaped to conform to the shape of the balloon.

In response to the present rejection applicant amended the claims to require that the claimed shaper "exhibits sufficient firmness such that the shaper can be used as a model to reconstruct the enlarged left ventricle." The examiner is of the position that the Deslauriers et al balloon is capable of such a use. The Deslauriers et al balloon is disclosed as having distinct shapes Figure 1 and

[1] In claims 5-7, applicant positively claims the fluid as part of the claimed balloon, whereas in claims 57, 58, 82, 83, 108, 109, 131, and 132 applicant only claims that the balloon is configured to contain particular types of fluid. Accordingly, claims 57, 58, 82, 83, 108, 109, 131, and 132 are interpreted as claiming only the balloon and not the combination of balloon and fluid.

Figures 8-10 that when inflated are nearly identical to the balloon shapes that applicant discloses and claims. The Deslauriers et al Figures illustrate the balloons inflated in open space where they inflate to the desired shape mimicing that of left ventricle, if they were inflated in an enlarged left ventricle they would likewise inflate to the same size and shape as when they are inflated in open space. The balloon size and shape could be used as a model by a surgeon in reshaping an enlarged left ventricle.

The firmness required for such a "model" (as it is claimed) could be quite minimal if used by the surgeon to simply act as a visual model, the "model" could be used simply for assisting a heart surgeon with a delicate touch in positioning the tissue about the model for suturing which would require only mild firmness or it could require extensive firmness if the surgeon tightly wrapped the tissues about the model. The claims give no hint as to what "firmness" would be required. Clearly the Deslauriers et al balloon has sufficient firmness for meeting the requirements of a visual model or a model where the skilled surgeon simply positioned the tissue about the balloon for the desired size and shape.

The 132 declaration of Mr. Mitta Suresh has been carefully considered. The examiner has readily admitted that the Deslauriers et al balloon was designed for a different use than that intended by applicant (aside from the overly broad method claims 168 and 169), that is not the issue. It is a well settled matter of patent law that a known prior art device does not become patentable merely because applicant has discovered some new use for that old and prior art device. The issue isn't whether applicant intends for a different use, but whether

there is a distinct physical difference between the claimed device and the prior art device. Applicant sets forth no such distinction in the present claims. Mr. Suresh's conclusionary opinion regarding the Deslauriers et al lack of firmness to serve as a "model" does not take into account the present claim language which simply calls for a "model." The opinion fails to state how much firmness is required of the claimed "model".

In response to the present rejection applicant refers to passages in Deslauriers et al that discuss a knitting which forms part of the balloon structure and that the construction is adaptable to any of the four heart chambers. In regard to the "knitting" structure disclosed by Deslauriers et al, the present claims all include the terminology "comprising" and "comprises" clearly indicating that the claim includes within its scope shapers having elements other than those specifically set forth in the claims. Moreover, it is noted that the knitting structure of the Deslauriers et al balloon helps the balloon to maintain its desired shape (column 16, line 68) and limits the inflation of the balloon to a predetermined volume (column 18, lines 15-18). In regard to the disclosure that the structure is adaptable to any of the four heart chambers, Deslauriers et al discloses specifically shaped balloons for the left ventricle (Figures 9 and 10), as well as, specifically shaped balloons for the other ventricles (Figures 8, 11, 12). More particularly, for a left ventricle having a pathological condition the balloon is shaped to be en elongated ellipsoidal shape (Figure 9), whereas for a normal shaped left vertical it is more of a cone/drop/pear shape (Figure 10). The Figure

9 and 10 left ventricle balloon embodiments of Deslauriers et al meet the "appropriate size and shape" limitations of the present claims.

Claims 1, 2, 36, 43, 45, 46, 48, 49, 50, 54-58, 64, 65, 74, 75, 79-83, 86, 90, 146-149, 153, 157-160, 164 168, 169, 186, 187 and 195-214 are rejected under 35 U.S.C. 102(b) as being anticipated by V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52).

Note Figure 2 and the second column of page 48 which discloses the repair of a patient's heart wherein an appropriately shaped balloon is inserted into the patient's left ventricle and inflated to the appropriate size (volume) (and inherently the appropriate shape), the left ventricle is reformed over the balloon and the appropriate sixed patch is determined from the ventricle reconstructed over the balloon, the balloon is then deflated and removed and the opening closed with the patch.

In response to the present rejection applicant argues that the V Dor et al balloon is used only for a volume determination and not the required shape. The examiner notes that the V. Dor et al balloon is illustrated as being ellipsoid, it is not square or rectangularly shaped, it is not shaped as a star or disk, but rather it is shaped and sized for providing the surgeon with a tool for determining the proper size and an appropriate shape for the reconstructed left ventricle. It serves as a model fro an appropriately shaped and sized left ventricle.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 7, 57, 58, 82, 83, 99-103, 108, 109, 117, 118, 131, 132, 177 and 178 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deslauriers et al (US 5,255,678) in view of Hillegass et al (US 4,817,637), Kovacs (US 5,749,839) and Cook et al (US 5,964,806).

Deslauriers et al indicates that the balloon member is filled with a saline solution rather than the claimed silicone gel. The prior art, however, is replete with teachings that silicone gel may conventionally be used in place of saline for inflating medical balloon devices as is evidenced for example by Hillegass et al (column 3, lines 59-60), Kovacs (column 3, line 61) and Cook et al (column 3, lines 49-53). To have selected silicone gel rather than saline for the balloon inflation fluid as is well known in the art would have been obvious to the ordinarily skilled artisan. In regard to claims 57, 58, 82, 83, 108, 109, 131, and 132, to the extent that one interprets the fluid to be positively claimed, the present rejection applies.

Claims 51- 53 and 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deslauriers et al (5,255,678).

One of ordinary skill in the art would have found the manufacture of the Deslauriers et al device with the particular thickness dimension claimed obvious as a matter of routine.

Claims 3-5, 36, 43, 47, 48, 51, 52, 59, 60, 76, 77, 84, 85, 150, 151, 161, 162, 168, 169, 186, 187, 215-217, 219-225, 229, 230, 233-235, 239 and 243-245 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52).

In regard to claims 3 and 4, V. Dor et al fail to disclose that the balloon once fully inflated that it cannot be substantially further expanded or that the balloon maintains its shape while being inflated, however, one of ordinary skill in the art would have found such limitations obvious in the design and construction of the disclosed balloon. The ordinarily skilled artisan would have been motivated to use a balloon that resisted further filling once full so as to not provide for too large of a size during the V. Dor et al procedure and certainly the ordinarily skilled artisan would desire a balloon that maintained it shape during this critical open heart surgery. In regard to claims 51, 52, 76 and 77, the claimed wall thickness for the balloon fall well within a range one of ordinary skill in the art would have found to have been obvious in constructing the V. Dor et al balloon.

Claims 6, 7, 57, 58, 82, 83, 99, 100, 177 and 178 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52) in view of Hillegass et al (US 4,817,637), Kovacs (US 5,749,839) and Cook et al (US 5,964,806).

V. Dor et al fails to disclose what type of fluid is used to inflate the disclosed balloon. The prior art, however, is replete with teachings that silicone gel may conventionally be used for inflating medical balloon devices as is evidenced for example by Hillegass et al (column 3, lines 59-60), Kovacs (column 3, line 61) and Cook et al (column 3, lines 49-53). To have selected silicone gel for the balloon inflation fluid as is well known in the art would have been obvious to the ordinarily skilled artisan. In regard to claims 57, 58, 82, and 83, to the extent that one interprets the fluid to be positively claimed, the present rejection applies.

Claims 8-12, 32-35, 61-70, 87-89, 91-95 152, 154, 163, 165, 218, and 223-228 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52) in view of Deslauriers et al (5,255,678).

In regard to claims 8-12, 61-63, 87-89, 152 and 163, V. Dor et al fail to disclose the specifically claimed structures in regard to the disclosed balloon.

Deslauriers et al, however, for a similar balloon used in the left ventricle teaches that a tube for conveying the inflation fluid, the use of a valve, pressure gauge and syringe are all desirable for controlling the inflation of a left ventricle balloon. To have merely used such common prior art features for controlling the inflation of the V.Dor et al balloon would have been obvious to one of ordinary skill in the art. In regard to claims 32-35, 64, 66-70, 91-95, 154 and 165, V.Dor et al fail to disclose the actual shape of the disclosed balloon. Deslauriers et al, however, teaches that it is desirable to form left ventricle balloons in the shape of a left ventricle which may be either ellipsoidal shape as in Figure 9 or drop/pear/cone shaped as in Figure 10. To have shaped the V.Dor et al balloon so that it was the shape of the left ventricle as taught by Deslauriers et al would have been obvious to one of ordinary skill in the art.

Claims 101-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over V. Dor et al ("Endoventricular Patch Reconstruction in Large Ischemic Wall-Motion Abnormalities," J. Cardiac Surg 199:14:46-52) in view of Hillegass et al (US 4,817,637), Kovacs (US 5,749,839) and Cook et al (US 5,964,806) as applied above and in further view of Deslauriers et al (US 5,255,678).

V. Dor et al fail to disclose the specifically claimed structures in regard to the disclosed balloon. Deslauriers et al, however, for a similar balloon used in the left ventricle teaches that a tube for conveying the inflation fluid, the use of a valve, pressure gauge and syringe are all desirable for controlling the inflation of

a left ventricle balloon. To have merely used such common prior art features for controlling the inflation of the V.Dor et al balloon would have been obvious to one of ordinary skill in the art.

Allowable Subject Matter

Claims 37-42, 44, 139, 140, 170-176, 179-185, 188-194, 234, 236-238 and 240-245 are objected to and would be allowable if rewritten in independent form to include all of the limitations of the claims from which they depend.

Action Made Final

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Ralph Lewis at telephone number (703) 308-0770. Fax (703) 872-9306. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Kevin Shaver, can be reached at (703) 308-2582.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.Lewis
August 23, 2004

Ralph A. Lewis
Primary Examiner
AU 3732